Claims

1. Method for preparing a sterile aqueous suspension of ciclesonide suitable for nebulization comprising the steps of:
   a. providing an aqueous suspension of ciclesonide, containing one or more pharmaceutically acceptable excipients, which one or more excipients are all non-ionic excipients; and
   b. autoclaving the aqueous suspension provided in (a).

2. Method for preparing a sterile aqueous suspension of ciclesonide suitable for nebulization comprising the steps of:
   a. providing an aqueous suspension of ciclesonide, containing at least one non-ionic agent for adjusting the osmolality and optionally further pharmaceutically acceptable excipients; and
   b. autoclaving the aqueous suspension provided in (a).

3. Method according to claim 1 or 2, wherein ciclesonide is selected from the group of [11β,16α(R)]--16,17-[(cyclohexylmethylene)bis(oxy)]- 11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4diene-3,20-dione, mixtures of the compounds [11β,16α(S)]-16,17-[(cyclohexylmethylene)bis-(oxy)]-11-hydroxy-21- (2-methyl1-oxopropoxy)pregna-1,4-diene-3,20-dione) and [11β,16α(R)]--16,17-[(cyclohexylmethylene)bis(oxy)]- 11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione in any desired mixing ratio, and mixtures of the compounds [11β,16α(S)]-16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21- (2-methyl1-oxopropoxy)pregna-1,4-diene-3,20-dione) and [11β,16α(R)]-16,17-[(cyclohexylmethylene)bis(oxy)]- 11-hydroxy--21-(2-methyl-1-oxopropoxy)pregna-1,4-diene3,20-dione which essentially consist of R epimers.

4. Method according to claim 1 or 2, wherein ciclesonide is selected from the group of ciclesonide, solvates of ciclesonide, physiologically functional derivatives of ciclesonide, solvates of physiologically functional derivates and mixtures thereof.

5. Method according to claim 4, wherein the physiologically functional derivative of ciclesonide is selected from the group of 16α,17-(22R)-cyclohexylmethylenedioxy-11β,21-dihydroxypregna-1,4--diene-3,20-dione, 16α,17-(22S)-cyclohexylmethylenedioxy-11β,21-dihydroxy-pregna-1,4-diene-3,20-dione, and mixtures thereof in any mixing ratio.

6. Method according to claim 1 or 2, wherein the mean particle size of ciclesonide is less than 12μm, preferably from 1 to 7μm, preferably 2 to 6μm, particularly preferably 2 to 4μm.

7. Method according to claim 2, wherein the non-ionic agent for adjusting the osmolality is selected from the group of mannitol, glycerol, glucose, lactose, trehalose, sucrose, propylene glycol, sorbitol, xylitol, polyethylene glycol, ethanol, isopropanol, cyclodextrins, derivatives of cyclodextrines and mixtures thereof.

8. Method according to claim 7, wherein the agent for adjusting the osmolality is selected from the group of mannitol, glycerol, glucose and mixtures thereof.

9. Method according to claim 1, wherein the suitable excipients are selected from the group of agents for adjusting osmolality, suspending agents, agents for modifying the pH of the suspension, chelating agents, preservatives and mixtures thereof.

10. Method according to claim 2, wherein the suitable excipients are selected from the group of suspending agents, agents for modifying the pH of the suspension, chelating agents, preservatives and mixtures thereof.

11. Method according to claim 10, wherein suitable excipients are non-ionic excipients.

12. Method according to claim 9 or 10, wherein an agent for modifying the pH of the suspension is present as excipients, which is an organic acid selected from the group of citric acid, tartaric acid, lactic acid and mixtures thereof.

13. Method according to claim 9 or 10, wherein the suspending agent is selected from the group of polysorbates, tyloxapol, poloxamers, poloxamines, polyoxyethylene castor oil derivatives, phospholipids, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, polyvinylpyrrolidone, polyvinylalcohol and mixtures thereof.

14. Method according to claim 13, wherein the suspending agents are polyoxyethylene sorbitan fatty acid esters (polysorbate).

15. Method according to claim 1, comprising the steps of

    a. dissolving the non-ionic excipients or excipients in water;
    b. optionally filtering the solution;
    c. homogeneously suspending ciclesonide within the solution and
    d. autoclaving the aqueous suspension provided in (c).

16. Method according to claim 2, comprising the steps of

    a. dissolving the non-ionic agent for adjusting the osmolality and optionally other excipients in water;
    b. optionally filtering the solution;
    c. homogeneously suspending ciclesonide within the solution; and
    d. autoclaving the aqueous suspension provided in (c).

17. Method according to any of the preceding claims, wherein autoclaving is carried out at a temperature above 90°C.

18. Method according to claim 17, wherein autoclaving is carried out at a temperature above 120° C.

19. Method according to claim 17, wherein autoclaving is carried out at 121°C for at least 15 minutes.

20. Method according to claim 1 or 2, wherein the sterile aqueous suspension of ciclesonide suitable for nebulization has an osmolality in the range of 225- 430 mosmol/kg, in the range of 250 to 350 mosmol/kg or in the range of 280 to 300 mosmol/kg.

21. Sterile aqueous suspension of ciclesonide suitable for nebulization containing one or more pharmaceutically acceptable excipients, which one or more excipients are all non-ionic excipients.

22. Sterile aqueous suspension of ciclesonide suitable for nebulization containing at least one non-ionic agent for adjusting the osmolality and optionally further pharmaceutically acceptable excipients.

23. Sterile aqueous suspension according to claims 21 or 22, having an osmolality in the range of 225- 430 mosmol/kg, in the range of 250 to 350 mosmol/kg or in the range of 280 to 300 mosmol/kg.

24. Sterile aqueous suspension according to claim 21 or 22, wherein the mean particle size of ciclesonide is less than 12µm, preferably from 0.1 to 8µm, preferably 1 to 6µm, particularly preferably 2 to 4µm.

25. Sterile aqueous suspension according to claim 22, wherein the non-ionic agent for adjusting the osmolality is selected from the group of mannitol, glycerol, glucose, lactose, trehalose, sucrose, propylene glycol, sorbitol, xylitol, polyethylene glycol, ethanol, isopropanol, cyclodextrins, derivatives of cyclodextrines and mixtures thereof.

26. Sterile aqueous suspension according to claim 25, wherein the agent for adjusting the osmolality is selected from the group of mannitol, glycerol, glucose and mixtures thereof.

27. Sterile aqueous suspension according to claim 21, wherein the suitable excipients are selected from the group of agents for adjusting osmolality, suspending agents, agents for modifying the pH of the suspension, chelating agents, preservatives and mixtures thereof.

28. Sterile aqueous suspension according to claim 22, wherein the suitable excipients are selected from the group of suspending agents, agents for modifying the pH of the suspension, chelating agents, preservatives and mixtures thereof. .

29. Sterile aqueous suspension according to claim 22, wherein suitable excipients are non-ionic excipients.

30. Sterile aqueous suspension according to claim 27 or 28, wherein an agents for modifying the pH of the suspension is present as excipients which is an organic acid selected from the group of citric acid, tartaric acid, lactic acid and mixtures thereof.

31. Sterile aqueous suspension according to claim 27 or 28, wherein the suspending agent is selected from the group of polysorbates, tyloxapol, poloxamers, poloxamines, polyoxyethylene castor oil derivatives, phospholipids, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, polyvinylpyrrolidone, polyvinylalcohol and mixtures thereof.

32. Sterile aqueous suspension according to claim 31, wherein the suspending agents polysorbate are polyoxyethylene sorbitan fatty acid esters (polysorbate).

33. Aqueous suspension of ciclesonide for administration by nebulization, wherein the concentration of ciclesonide within the suspension for nebulization is in the range of 0.005% to 0.5% (w/v) (i.e. 0.05 mg/ml to 5mg/ml).

34. Aqueous suspension according to claim 21, 22 or 33, wherein the mean particle size of ciclesonide is less than 12µm, preferably from 0.1 to 8µm, preferably 1 to 6µm, particularly preferably 2 to 4µm.

35. Aqueous suspension of ciclesonide according to claim 33, which is a sterile suspension.

36. Aqueous suspension of ciclesonide according to claim 33, which is a formulation according to claim 21 or 22.

37. Sterile aqueous suspensions according to claim 21 or 22 containing as excipients mannitol and polysorbate or glycerol and polysorbate.

38. Sterile aqueous suspension according to claim 37, additionally containing hydrochloric acid or citric acid.

39. Method for the prophylaxis or treatment of a clinical condition in a patient for which a glucocorticosteroid is indicated, which comprises administration of a therapeutically effective amount of a sterile aqueous suspension of ciclesonide according to claim 21, 22 or 33.

40. Method according to claim 39, wherein the clinical condition is asthma the patient is a child and the treatment is a continuous treatment regimen and the sterile aqueous suspension of ciclesonide is administered by nebulization.

41. Drug product comprising a sealed container containing a sterile aqueous suspension according to claim 21, 22 or 33, and a label indicating administration by nebulization in a continuous treatment regimen.